APR 1 1 2001

K 003126

ellman international inc.
510 (k) Premarket Notification
Bipolar TRIGGER-FLEX™ Electrode

510 (k) Summary of Safety and Effectiveness

SUBMITTER: ellman international inc.
1135 Railroad Avenue
Hewlett, New York 11557

CONTACT PERSON: Frank Lin, Director of Engineering

DATE PREPARED: April 15, 2000

CLASSIFICATION NAME: Electrosurgical Cutting and Coagulation Device and Accessories

COMMON/USUAL NAME: Bipolar Forceps

PROPRIETARY NAME: Bipolar TIGGER-FLEX™ Electrode

PREDICATE DEVICES: Select-Sutter Micro-Bipolar Forceps, (K992760)
Select Medizin-Technik Hermann sutter GmbH

DEVICE DESCRIPTION: The Bipolar TIGGER-FLEX™ Electrode is a laparoscopic and endoscopic device used for the grasping and general coagulation/cutting and pinpoint coagulation of tissue using electrosurgical energy under visualization. The device is used with bipolar outputs of electrosurgical generators for grasping/coagulation and pinpoint coagulation. The Bipolar TIGGER-FLEX™ Electrode is a sterile single-use packaged device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2001

Frank Lin, Ph.D.
Director of Engineering
Research and Development Department
Ellman International, Inc.
1135 Railroad Avenue
Hewlett, New York 11557

Re: K003126
Trade/Device Name: Bipolar TIGGER-FLEX™ Electrode
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: January 29, 2001
Received: January 30, 2001

Dear Dr. Lin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003126

Device Name: TRIGGER-FLEX™ Bipolar Electrode

Indication For Use:

The TRIGGER-FLEX™ Bipolar Electrode is intended for use by a physician familiar with electrosurgery in bipolar coagulation for general surgery where coagulation of soft tissue is needed. This product is used with bipolar output of standard electrosurgical generators. The types of surgery intended are:

* General surgery
* Laparoscopic procedures
* Endoscopic procedures
* Laryngeal coagulation
* Orthopedic coagulation
* Thorascopic coagulation
* Neurosurgical coagulation
* Gynecological coagulation, (except for use in female sterilization)
* Ear, Nose and Throat coagulation

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003126